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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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		Application No.	Applicant(s)	
		10/708,723	SCHMIDT, EHUD J.	
Office Action Sumn	nary	Examiner	Art Unit	
		ELLSWORTH WEATHERBY	3768	
The MAILING DATE of this openiod for Reply	communication appe	ears on the cover sheet with th	e correspondence address	
A SHORTENED STATUTORY PE WHICHEVER IS LONGER, FROM - Extensions of time may be available under the after SIX (6) MONTHS from the mailing date of - If NO period for reply is specified above, the n - Failure to reply within the set or extended peri Any reply received by the Office later than thre earned patent term adjustment. See 37 CFR	THE MAILING DA provisions of 37 CFR 1.130 If this communication. Inaximum statutory period will for reply will, by statute, we months after the mailing	TE OF THIS COMMUNICATI 6(a). In no event, however, may a reply be Ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDO	ON. timely filed om the mailing date of this communicati NED (35 U.S.C. § 133).	
Status				
•	2b)☐ This a	/ <u>/2010</u> . action is non-final. ce except for formal matters, x <i>part</i> e Q <i>uayle</i> , 1935 C.D. 11,		is
Disposition of Claims				
4)	is/are withdrawed. 32 is/are rejected. ed to.	n from consideration.		
Application Papers				
•	_ is/are: a) ☐ acce any objection to the d including the correction	pted or b) objected to by the lrawing(s) be held in abeyance. Son is required if the drawing(s) is	See 37 CFR 1.85(a). objected to. See 37 CFR 1.121	(d).
Priority under 35 U.S.C. § 119				
	ne of: priority documents priority documents copies of the priori sternational Bureau	have been received. have been received in Applic ty documents have been rece (PCT Rule 17.2(a)).	ation No ived in this National Stage	
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing 3) Information Disclosure Statement(s) (PTO Paper No(s)/Mail Date		4) Interview Summ. Paper No(s)/Mai 5) Notice of Informa 6) Other:		

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DETAILED ACTION

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1 and 4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al. (USPN 6,628,980) in view of Karmarkar et al. (Pub. No.: 2004/0046557).
- 3. Regarding claims 1, 4 and 16, Atalar et al. (hereinafter Atalar) teaches a probe for acquiring data in a magnetic resonance imaging (Abstract; Figs. 1-18), comprising: A self expanding distal head insertable into a subject's vascular system to be imaged and constructed to permit fluid or blood flow therethrough (col. 3, lines 55-67; col. 4, lines 1-5; col. 14, II. 30-65; col. 19, lines 50-56 See also Distal head of Figure 6D). Here, the distal region comprises an imaging coil (644), comprising a plurality of RF coils (607a, 607b) that are expandable when tubular member (698) is retracted. For example, Atalar teaches a multi coil MRI probe comprising an expandable probe (870) that is advanced so that the RF coil (804) protrudes from the sleeve (868) (col. 16, II. 29-37). In the expanded state, the coil (804) forms a gap between the coil (804) and the nested expandable probe (870). Another embodiment that reads on the present claim 1 is

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described by Figures 8A-B or 9A-B. Here, a loop imaging coil (972) is inserted into a loopless imaging coil sleeve (974) (col. 16, l. 50-col 17, l. 24). Furthermore, the gap between the housing and the coil (804) is configured to increase RF sensitivity away from the probe (col. 16, l. 64- col. 17, l. 24). Also, the MRI sleeve and probe may comprise one or more imaging coils (col. 16, ll. 59-63; col. 17, ll. 19-24). Therein, Atalar teaches that the combination provides a sensitivity profile combining the strengths of both types of coils is achieved.

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4. **Regarding claims 6-9**, Atalar also teaches a shaft connected to the housing and constructed to position the housing within the subject to be imaged (col. 4, lines 40-43). Atalar et al. '980 also teaches a retractable sheath constructed to enclose the housing during insertion into the subject and translation to a target tissue to be imaged and further constructed to be retracted by a user to allow the housing to expand when proximity to the target tissue is reached (col. 16, lines 29-31). Atalar et al. '980 also teaches that the sheath is constructed to enclose the housing during insertion into the subject and translation to a target tissue to be imaged and further constructed to be retracted by a user to allow the housing to expand when proximity to the target tissue is reached (col. 15, lines 66-67; col. 16, 1-11; col. 16, lines 29-31). Atalar et al. '980 also teaches that the sheath is formed of a material that applies a compression force upon the housing and the plurality RF coils during insertion into the subject and translation to the target tissue to be imaged, and wherein the housing is constructed of material to automatically expand the plurality RF coils when the compression force is removed, and

further, that the sheath has a shaft that exceeds a distance from an insertion point to the

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target tissue to be imaged (col. 15, lines 66-67; col. 16, 1-37).

5. Regarding claims 10-14, Atalar teaches that the housing comprises a first pair of bars and a second pair of bars in first and second orthogonal planes forming the first and second RF loop coils, comprising a nitinol and insulating material (col. 14, II. 30-67; refs. 607A-B).

6. Atalar discloses as well known that loop imaging coils provide near field imaging with increased sensitivity distributed across their length (col. 17, II. 1-15). It is within reason that one of ordinary skill in the art would interpret the gap formed between the plurality of expanded RF coils and the housing to be met by the expanded loop coils of Atalar. However, if it is interpreted that Atalar does not expressly teach that the RF coils attachment means to the housing forms a gap, there is nothing in the disclosure to show why the multiple expandable coils of Atalar is not an obvious variant of the present application's gap formed between the RF coils and housing, because both Atalar and the present invention are concerned with achieving the same function of increasing RF sensitivity away from the probe. Furthermore, because Atalar so clearly anticipates each and every other limitation and even obviates the claimed attachment limitation, e.g. incorporating by reference USPN 5,699,801, USPN 5,928,145 and USPN 5,928,145 as alternative coil designs for use within the expandable device (col. 9, Il. 22-29; col. 12, II. 43-64; col. 13, II. 15-27), the Examiner had taken the stance that the disclosure of Atalar obviates the presently claimed invention by the 01/26/2010 Non Final Rejection. Quoting Atalar, "The detector coil (504) may comprise a loopless

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imaging coil or a loop imaging coil of any type known in the art, including those types described above and by Ocali et al. in U.S. Pat. No. 5,928,145, by Atalar '801, and by Atalar '229.". As an example of the obviousness of attaching RF coils to expandable members similar to those of Atalar, the Examiner sets forth the following reference.

- 7. In the same field of endeavor, Karmarker et al. teaches an intra-cardiac magnetic resonance probe (Abstract; Figs. 1-10C). Karmarker goes on teaching an expandable basket similar to that disclosed by Atalar (Figs. 6A-D). Here, Karmarker teaches that each expandable arm comprises a plurality of electrodes (0069). Karmarker goes on, further teaching that the electrodes disposed on the arm may be glued or bonded (0070). Karmarker further teaches that miniature loop coils may be placed adjacent to the one or more electrodes attached to the radially expandable housing (0070).
- 8. The Examiner stands that it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the expandable housing and imaging coils of Atalar in view of the attachment means for an RF coil to an expandable housing of Karmarkar. The motivation to modify Atalar in view of Karmarkar would be to recognize that Atalar's contribution to the art and to utilize any known RF coil and attachment means such that the variety of imaging coils as suggested by Atalar may be attached to the expandable housing.
- 9. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al. (USPN 6,628,980) in view of Karmarkar et al. (Pub. No.: 2004/0046557) as applied to claim 1 above, and further in view of Nevo et al. (USPN 6,516,213).

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10. The expandable imaging device of Atalar in view Karmarkar teaches all the limitations of the claimed invention except for expressly teaching that a tracking coil is configured to transmit tracking signals for gating data acquisition.

- 11. In the same field of endeavor, Nevo et al. (hereinafter Nevo) teaches a method and apparatus to estimate location and orientation of object during MRI (Abstract; Figs. 1-7). Nevo goes on teaching using tracking coils, which are configured to transmit tracking signals for gating data acquisition (col. 14, II. 21-40; col. 15, II. 8-55). Nevo also teaches utilizing the system for tracking catheters in intra-cardiac procedures (col. 13, I. 55- col. 14, I. 18).
- 12. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the expandable RF probe of Atalar in view of Karmarkar with the tracking coils for gating acquisition of Nevo. The motivation to modify Atalar in view of Karmarkar with Nevo would have been to provide accurate readings of position or orientation of an intra-cardiac probe throughout the procedure where the position data is acquired using known tracking coils, as taught by Nevo.
- 13. Claims 26-28 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al. (USPN 6,628,980) in view of Karmarkar et al. (Pub. No.: 2004/0046557) and Nevo et al. (USPN 6,516,213).
- 14. The expandable imaging device of Atalar in view Karmarkar teaches all the limitations of the claimed invention, as noted above. However, Atalar in view of Karmarkar does not expressly teach that a tracking coil is configured to transmit

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tracking signals for gating data acquisition. Atalar in view of Karmarkar also does not expressly teach that the device is an intra-cardiac device.

- 15. In the same field of endeavor, Nevo et al. (hereinafter Nevo) teaches a method and apparatus to estimate location and orientation of object during MRI (Abstract; Figs. 1-7). Nevo goes on teaching using tracking coils, which are configured to transmit tracking signals for gating data acquisition (col. 14, II. 21-40; col. 15, II. 8-55). Nevo also teaches utilizing the system for tracking catheters in intra-cardiac procedures (col. 13, I. 55- col. 14, I. 18). Here, the Examine that the combination of Atalar in view of Karmarkar and Nevo provides instantaneous tracking the device at any time, including prior to retracting the sheath (See Nevo: Abstract).
- 16. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the expandable RF probe of Atalar in view of Karmarkar with the tracking coils for gating acquisition of Nevo. The motivation to modify Atalar in view of Karmarkar with Nevo would have been to provide accurate readings of position or orientation of an intra-cardiac probe throughout the procedure where the position data is acquired using known tracking coils, as taught by Nevo.
- 17. Claims 17 and 19-21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (USPN 6,292,683) in view of Atalar et al. (USPN 6,628,980) and Nevo et al. (USPN 6,516,213).
- 18. Gupta et al. (hereinafter Gupta) teaches an MRI apparatus (Abstract: Figures 1-4), comprising: a magnetic resonance imaging (MRI) system having a plurality of

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assembly.

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gradient coils positioned about bore of a magnet to impress a polarizing magnetic field and an RF transceiver system and an RF switch controlled by a pulse module to transmit RF signals to an RF coil assembly to acquire MR images (col. 3, II. 42-65), the RF assembly being used to track the motion of a medical instrument (col. 3, II. 26-41).

19. Gupta does not expressly teach that the RF coil assembly comprises an intracardiac catheter configured for insertion into a blood flow and constructed to automatically expanded position from a compressed position; a plurality of RF coils connected to the catheter and configured to acquire MR data; a tracking coil connected to the catheter and configured to acquire MR data; a tracking coil connected to the catheter and configured to indicate RF coil assembly location and movement within an imaging subject; wherein the tracking coil is configured to transmit signal indicating the location and movement of the RF coil assembly to the MRI system to facilitate MR data acquisition gating; and wherein the MRI system is configured to gate MR data acquisition during imaging based on the location and movement of the RF coil

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20. In a related field of endeavor, Atalar et al. (hereinafter Atalar) teaches a probe for acquiring data in a magnetic resonance imaging (Abstract; Figs. 1-18), comprising: A self expanding distal head insertable into a subject's vascular system to be imaged and constructed to permit fluid or blood flow therethrough (col. 3, lines 55-67; col. 4, lines 1-5; col. 14, II. 30-65; col. 19, lines 50-56 See also Distal head of Figure 6D). Here, the distal region comprises an imaging coil (644), comprising a plurality of RF coils (607a, 607b) that are expandable when tubular member (698) is retracted (In this regard the

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RF coils are connected to the catheter and configured to acquire MR data). For example, Atalar teaches a multi coil MRI probe comprising an expandable probe (870) that is advanced so that the RF coil (804) protrudes from the sleeve (868) (col. 16, II. 29-37). Atalar further teaches that the expanded diameter substantially matches an inner diameter of a target tissue in which the probe is placed (claim 49). Atalar teaches that the housing comprises a first pair of bars and a second pair of bars in first and second orthogonal planes forming the first and second RF loop coils, comprising a high memory nitinol and insulating material (col. 14, II. 30-67refs. 607A-B: Here, the Examiner notes that the upon retraction of the sheath the plurality of RF coils are configured to automatically expand from a compressed position).

- 21. Atalar does not expressly teach that the catheter is an intra-cardiac catheter or that the tracking coil is configured to transmit tracking signals for gating data acquisition.
- 22. In the same field of endeavor, Nevo et al. (hereinafter Nevo) teaches a method and apparatus to estimate location and orientation of object during MRI (Abstract; Figs. 1-7). Nevo goes on teaching using tracking coils configured to transmit tracking signals for gating data acquisition (col. 14, II. 21-40; col. 15, II. 8-55). Nevo also teaches utilizing the system for tracking catheters in intra-cardiac procedures (col. 13, I. 55- col. 14, I. 18).
- 23. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the MRI system for tracking medical devices of Gupta in view of the expandable RF probe of Atalar and the tracking coil for gating acquisition of Nevo. The

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motivation to modify Gupta in view of Atalar and Nevo would have been to provide dynamic intra-cardiac imaging using known devices or techniques.

- 24. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (USPN 6,292,683) in view of Atalar et al. (USPN 6,628,980) and Nevo et al. (USPN 6,516,213) as applied to claim 21 above, and further in view of Karmarkar et al. (Pub. No.: 2004/0046557).
- 25. Gupta et al. (USPN 6,292,683) in view of Atalar et al. (USPN 6,628,980) and Nevo et al. (USPN 6,516,213) teach all the limitations of the claimed invention. However, Applicant contests the obviousness of the claimed RF coil attachment to the bars that was set forth in the 1/26/2010 Non-Final Rejection. However, as noted above, Atalar discloses as well known that loop imaging coils provide near field imaging with increased sensitivity distributed across their length (col. 17, II. 1-15). If it is interpreted that Atalar does not expressly teach that the claimed RF coils attachment means to the housing, there is nothing in the disclosure to show why the multiple expandable coils of Atalar is not an obvious variant of the present application's RF coils attached to first and second set of bars, because both Atalar and the present invention are concerned with achieving the same function of increasing RF sensitivity away from the probe. Furthermore, because Atalar so clearly anticipates each and every other limitation and even obviates the claimed attachment limitation, e.g. incorporating by reference USPN 5,699,801, USPN 5,928,145 and USPN 5,928,145 as alternative coil designs for use within the expandable device (col. 9, II. 22-29; col. 12, II. 43-64; col. 13, II. 15-27), the

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Examiner had taken the position that the disclosure of Atalar obviates the presently claimed invention. Quoting Atalar, "The detector coil (504) may comprise a loopless imaging coil or a loop imaging coil of any type known in the art, including those types described above and by Ocali et al. in U.S. Pat. No. 5,928,145, by Atalar '801, and by Atalar '229.". As an example of the obviousness of attaching RF coils to expandable members, the examiner sets forth the following reference.

- 26. In the same field of endeavor, Karmarker teaches an intra-cardiac magnetic resonance probe (Abstract; Figs. 1-10C). Karmarker goes on teaching an expandable basket similar to that disclosed by Atalar (Figs. 6A-D). Here, Karmarker teaches that each expandable arm comprises a plurality of electrodes (0069). Karmarker goes on, further teaching that the electrodes disposed on the arm may be glued or bonded (0070). Karmarker further teaches that miniature loop coils may be placed adjacent to the one or more electrodes attached to the radially expandable housing (0070).
- 27. As noted above, Atalar was set forth as obviating the claimed first set of bars attached to the first RF coil and second set of bars attached to the second coil. However, Applicant contests that obviousness. The Examiner stands that because Atalar suggests using a plurality of detector coil designs, e.g. incorporating by reference USPN 5,699,801, USPN 5,928,145 and USPN 5,928,145, and noting that the detector coil may comprise a loopless imaging coil or a loop imaging coil of any type known in the art, it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the expandable housing and imaging coil of Atalar in view of the attachment means for an RF coil to an expandable housing of Karmarkar . The

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motivation to modify Atalar in view of Karmarkar would be to recognize that Atalar's contribution to the art and to utilize any known RF coil and attachment means such that the variety of imaging coils as suggested by Atalar may be attached to the expandable housing.

Response to Arguments

- 28. Applicant's arguments filed 04/21/2010 have been fully considered but they are not persuasive.
- 29. Regarding the rejection of claims 1 and 4-16 under 35 U.S.C. 102(b) as anticipated by or in the alternative 35 U.S.C. 103(a) as obvious over Atalar, Applicant alleges that the Examiner has improperly stretched the teaching of Atlar in order to reflect that called for in claim 1. Applicant alleges that Atalar does not teach the structural limitations of claim 1, nor are those limitations obvious over the teachings of Atalar. Specifically, Applicant alleges that Atalar does not teach a plurality of RF coils and a self-expanding housing. The Examiner respectfully disagrees. Here, the Examiner relied on Atalar to teach the auto-expansion of the RF coils to increase RF sensitivity away from the probe (e.g. near field away from the probe). It appears that it is Applicant's position that the limitation calling for an attachment means of an RF coil to a medical device differentiates the present invention from the prior art. Here, the Examiner respectfully disagrees. That is, in the field of near-field RF imaging the SNR falls off precipitously as the radial distance from the coil increases (See Figs. 10A-10C). These figures illustrate Atalar's recognition that the further the coil is from the probe the

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better the signal to noise ratio (e.g. analogous to the gap configured to increase RF sensitivity away from the probe). Thus, Atalar was motivated to invent a probe where a plurality of RF Coils are provided together with a self-expanding housing insertable into a subject to be imaged and constructed to permit fluid flow there through (Figs. 7-7A). Applicant continues to argue that because Atalar does not teach the additional elements that may be called a plurality of RF coils and expandable elements such that a gap is formed between the RF coils and the core, that the present invention is distinct from the prior art. This type of variation has been specifically addressed by the Supreme Court: 30. In KSR, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art,"ld. at 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."Id. at , 82 USPQ2d at 1395. The Supreme Court stated that there are "[t]hree cases decided after Graham [that] illustrate this doctrine." Id. at , 82 USPQ2d at 1395. (1) "In United States v. Adams, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." Id. at ____, 82 USPQ2d at 1395. (2) "In Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., . . . [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation."Id. at ____, 82 USPQ2d at

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1395. (3) "[I]n Sakraida v. AG Pro, Inc., the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." Id. at _____, 82 USPQ2d at 1395-96 (Internal quotations omitted.). The principles underlining these cases are instructive when the question is whether a patent application claiming the combination of elements of prior art would have been obvious. The Supreme Court further stated that: When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Id. at ____, 82 USPQ2d at 1396.

31. Because Atalar so clearly anticipates or makes obvious each and every single limitation of the claimed invention, even incorporating by reference USPN 5,699,801, USPN 5,928,145 and USPN 5,928,145, the Examiner had taken the position that the disclosure of Atalar obviates the presently claimed invention in the 01/26/2010 Non-Final Rejection. Quoting, Atalar, "The detector coil (504) may comprise a loopless imaging coil or a loop imaging coil of any type known in the art, including those types described above and by Ocali et al. in U.S. Pat. No. 5,928,145, by Atalar '801, and by Atalar '229.".

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32. Therefore, the Examiner asserts that the present invention is indeed made obvious over the teachings of Atalar. Therefore, as a measure to facilitate the prosecution the Examiner has set forth an additional reference to highlight, as a mere example, why it would be a mere obvious variation of the teachings of Atalar to include attachment means for RF coils to the expandable housing. This rejection is not necessitated, but is set forth merely to highlight the obviousness of attaching an RF coil to an expandable bar in view of the disclosure of Atalar, as was set forth in the previous 1/26/2010.

Conclusion

33. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number

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is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00

p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

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/EW/

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768